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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/564,579

05/10/2006

Daisuke Shii

06019/HG

2031

1933 7590 11/13/2008  
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EXAMINER

EBRAHIM, NABILA G

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

11/13/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/564,579	<b>Applicant(s)</b> SHII ET AL.	
	<b>Examiner</b> Nabila G. Ebrahim	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 3, 12 and 14-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3, 12, and 14-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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**DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/27/2008 has been entered.

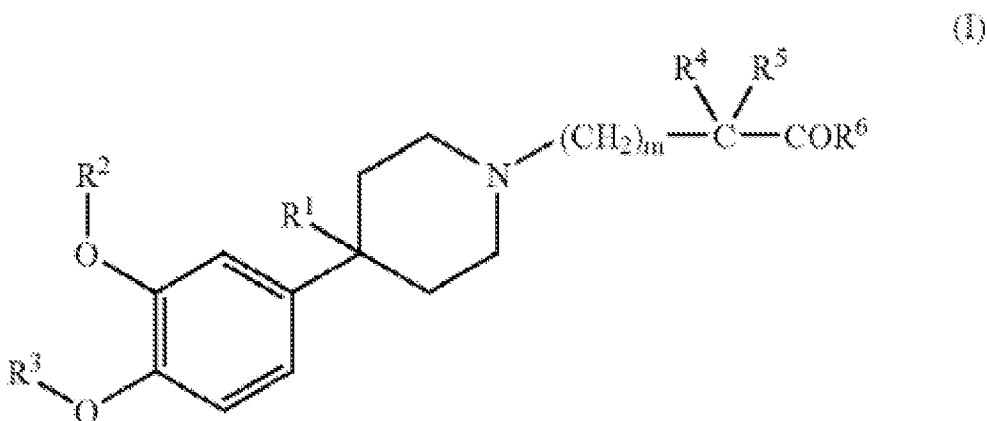
**Status of claims:** 3, 12, 14-18 are pending in the application.

**Claim Rejections - 35 USC § 103**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 3, 12, 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakai et al. WO 0214280 in view of Gamache et al. US 6872382 (Gamache).

Nakai teaches the same compound as shown (see abstract, and page 4, lines 11+ for detailed description of the compound)



Nakai discloses that the agents which specifically inhibit PDE4 are useful in treating various diseases such as allergic diseases (e.g., allergic rhinitis, allergic conjunctivitis, seasonal

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conjunctivitis, atopic dermatitis, etc.), see page 2, lines 42+. Note that allergic rhinitis, allergic conjunctivitis, seasonal conjunctivitis cause eye pruritus as required by the instant claims. The compound represented by formula (I) may be administered in the form of liquid compositions such as eye lotion (page 27, lines 54+) and eye ointment (page 28, lines 29+).

Nakai also discloses that the dosages are determined depending on age, body weight, symptom, therapeutic effect, administration route, duration of the treatment and the like. Generally, 1 mg to 1000 mg per adult is orally administered once to several times per day (page 27, lines 48+). The reference also teaches the use of an alkali metal hydroxide e.g., sodium hydroxide and a surfactants e.g., POLYSORBATE80 [0059]. Nakai is deficient in using the piperidine compound in eye drops.

Gamache teaches PDE IV inhibitors to treat dry eye disorders (note that the dry eye syndrome includes itch as one of its symptoms). The reference teaches eye drops that comprises an amount of selective PDE-IV inhibitor 0.001-1.0 % W/V of the PDE IV (example 1). The eye drops contain sodium hydroxide (example 1), compositions administered according to the present invention may also include various other ingredients, including but not limited to surfactants, tonicity agents, buffers, preservatives, co-solvents and viscosity building agents (col. 4, lines 20+ and example 1).

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make to use the compound disclosed by Nakai in eye drops as taught by Gamache and in the same amount to treat eye itch since both references teach that the PDE IV inhibitors are able to treat eye disorders that have itch as a symptom. The skilled artisan would have good expectation of treating itchy eyes by using eye drops comprising PDE IV inhibitors.

### ***Response to Arguments***

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2. Applicant's arguments with respect to claims 3, 12, 14-18 have been considered but are moot in view of the new ground(s) of rejection.

Applicant argues Thompson US 5756508 in view of the compounds disclosed and amount of active ingredient in the eye drops disclosed. However, Thompson is not included in the new grounds of rejection.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nabila G Ebrahim/  
Examiner, Art Unit 1618

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit  
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